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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hao Chen

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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/669,705	Applicant(s) CHEN ET AL.	
	Examiner PABLO WHALEY	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 38, 40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 38, 40, and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request For Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/27/2008 has been entered.

Status of the Claims

Claims 1-8 and 38, 40, and 41 are pending.

Claims 1-8 and 38, 40, and 41 are rejected.

Claims 9-37 and 39 are cancelled.

Priority

Applicant's amendment of the claims to recite "recursive" partitioning in the response filed 08/27/2008 has clarified the issue of priority. Accordingly, this application has been granted to benefit of priority to application 10/105,407, filed 4/26/2000. However, application 10/105,407 claims benefit to Provisional Application No. 60/130,992, which does not provide support for "recursive partitioning," as in claims 8 and 41. For these reasons, applicants are not given benefit of priority to Provisional Application No. 60/130,992 for claim numbers 8 and 41.

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Withdrawn Rejections

The rejection of claim 3 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendments, filed 08/27/2008.

The rejection of claims 3 and 7 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments, filed 08/27/2008.

The rejection of claims 1, 2, 4-7, and 40 are rejected under 35 U.S.C. 102 (b) as being anticipated by Nilakantan et al. is withdrawn in view of applicant's amendments and arguments directed to a "full-rank" database, filed 08/27/2008.

The rejection of claims 1-8, 38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being made obvious by Nilakantan et al. in view of Chen et al. Grass et al. is withdrawn in view of applicant's amendments and arguments directed to a "full-rank" database, filed 08/27/2008.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 38, 40, and 41 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

For a process that comprises an abstract idea to be statutory, it must comprise a practical application of the abstract idea. Claimed subject matter may require a practical application by claiming, or requiring use of, a machine, or by requiring a physical transformation of an article to a different state or

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thing [In Re Bilski (88 USPQ2d 1385 Fed. Cir. 2008)]. Even if claimed subject matter claims, or requires use of, a machine, the claimed subject matter may not require a practical application. However, one indication that claimed subject matter requires a practical application is an explicit requirement of a useful concrete, and tangible result [In re Alappat (31 USPQ2d 1545 Fed. Cir. 1994)]. As a result, for an apparatus, program, or system carrying out a process that comprises an abstract idea to be statutory, the machine, program, or system must also provide a concrete, tangible, and useful result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be “useful” the claim must produce a result that is specific and substantial. For a claim to be “concrete” the process must have a result that is reproducible. For a claim to be “tangible” the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-8, 38, 40, and 41 do not require production of a tangible result in a form that is understandable to the user of the process or apparatus. In particular, claims 1 and 5 result in “providing output” of data, which reads on outputting data to a memory. It is noted that the suggested remedy in the final action, mailed 07/09/2007, was adopted by the applicants. However, we have changed our requirements for an explicit tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

This rejection is newly applied.

Claims 1-8, 38, 40, and 41 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

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The claimed subject matter is directed to a process for drug discovery and development. A claimed process is statutory under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter), or (2) it transforms a particular article into a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008; In re Comiskey, Fed. Cir., No. 2006-1286).

Regarding the required tie to a particular machine or apparatus, the claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant data gathering or post-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

Regarding the transformation test, the claimed subject matter does not recite a physical transformation of matter. This rejection could be overcome by amendment of the claims to recite a step wherein an article is reduced to a different state or thing (e.g. physical assay), or a step wherein data representing a physical object or substance that is obtained by a specific physical process is sufficiently manipulated or changed (e.g., raw data into a particular visual depiction of a physical object on a display) [See In re Abele, 684, F.2d at 908-909, CCPA, 1982]. The applicants are cautioned against introduction of new matter in an amendment.

Response to Arguments

Applicant's arguments, filed 08/27/2008, that the claimed subject matter now recites a concrete, tangible, and useful result have been fully considered. In response, claims 1-8, 38, 40, and 41 do not

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require production of a tangible result in a form that is understandable to the user of the process or apparatus. In particular, claims 1 and 5 result in “providing output” of data, which reads on outputting data to a memory. It is noted that the suggested remedy in the final action, mailed 07/09/2007, was adopted by the applicants. However, after further consideration the suggested remedy of outputting to a memory is no longer considered by the Office to be sufficient for establishing a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. This rejection is maintained. Applicants are cautioned against introduction of new matter in an amendment. In addition, a new ground of rejection has been applied, as set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being made obvious by Weinstein et al. (Science, 1997, Vol. 275, p. 343-349), in view of Chen et al. (J. Chem. Inf. Comput. Sci., 1998, Vol. 38, p.1054-1062).

Instant claims 1 and 5 require a “full-rank” database of interactions. It is noted that the instant specification discloses a database that is considered a full-rank database “in terms of protein-ligand binding, which means that binding data of each compound is tested against each protein available regardless of whether it is inactive or active” [p.15]. For purposes of examination, the full-rank database is interpreted to be a database that comprises molecular binding information for each compound being tested.

Weinstein teaches a drug discovery method for developing anti-cancer compounds. In particular, Weinstein provides databases comprising molecular structural descriptors, activity, and molecular targets [Abstract, Fig. 1] for testing thousands of known compounds. Weinstein selects a plurality of molecular targets associated with anti-cancer activity [Fig. 3]. Weinstein analyzes the above databases to identify the relationships between thousands of compounds and molecular targets associated with cancer [Fig. 2 and p.345, Col. 3], including compounds that are highly positive (red) and highly negative (blue) in their correlation with specific targets [p.346, Col. 3, and Fig. 3], wherein the negative correlations are inherently associated with undesired therapeutic. A plurality of candidate compounds are selected and output by computer programs as potential drugs to treat cancer [p.347, Col. 3, ¶4]. The molecular descriptor database comprises elements that represent both 2D and 3D both structure [Fig. 2, p.344, Col.

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2]. Weinstein identifies compounds that act as cytotoxic agents [p.347, Col. 3, ¶2], which shows undesired therapeutic effects.

Weinstein does not specifically teach a "full-rank" database, as in claims 1 and 5.

Weinstein does not specifically teach an undesired therapeutic effect that is a side effect, as in claim 8. However, it would have been obvious to one of ordinary skill in the art to include information related to side effects since Weinstein already identifies candidate compounds that are highly correlated to drugs which are well known to have toxic effects [p.347, Col. 3, ¶2]. The motivation would have been to provide a more robust screening process that identifies potential drug compounds and their effects.

Weinstein does not teach recursive partitioning for analyzing database, as in claims 8 and 41.

Chen teaches a method of drug discovery and development [Abstract]. In particular, Chen teaches a database comprising binding information for active and inactive compounds represented by 3-D descriptors that describe structural features of compounds [p.1054, Col. 2, and p.1055, Methods, Col. 1 and Col. 2] . Chen teaches recursive partitioning analysis for analyzing said database to determine structure-activity relationships and identify candidate compounds [Abstract, p.1056, Col. 1, SCAM/RP]. Chen suggests adding more concepts to molecular descriptors to provide more information about the interaction between compounds and their receptors [p.1061, Col. 2, ¶2].

It would have been obvious to one of ordinary skill in the art to provide a "full-rank" database of interactions by expanding the target database of Weinstein to include binding information for each compound, as taught by Chen [p.1055, Methods], since Weinstein provides database that related activity with target patterns [Fig. 2 and p.345, Col. 3, ¶2]. The motivation would have been to provide a more robust screening process by adding more concepts to molecular descriptors to provide more information about the interaction between compounds and their receptors, as suggested by Chen [p.1061, Col. 2, ¶2].

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It would further have been obvious to someone of ordinary skill in the art at the time of the instant invention to analyze the database taught by Weinstein using the recursive partitioning method of Chen, since Chen's method is inherently faster at analyzing large databases than the clustering method taught by Weinstein [Introduction, p.1054, Col. 2], and since Weinstein teaches large data sets containing 2D and 3D structural descriptors and compounds. The motivation would have been to perform database analysis using an improved method for grouping compounds, displaying information, and uncovering new relationships between molecular targets and compounds, as suggested by Chen [Introduction, p.1054, Col. 2].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631